IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA

v.

URSULA WING,

Defendant.

INDICTMENT

Case No. 19 CR 84 JDP

18 U.S.C. § 371
21 U.S.C. § 331(a)
21 U.S.C. § 333(a)(2)
21 U.S.C. § 334(d)(3)
21 U.S.C. § 853 (p)
28 U.S.C. § 2461(c)

THE GRAND JURY CHARGES:

COUNT 1

Factual Background

1. At times material to this indictment:

a. Defendant URSULA WING was a resident of New York City, New York. WING operated a blog under the name "the Macrobiotic Stoner," and ran it from her home in New York City. WING also operated a fake jewelry business under the name Morocco International Inc., which she used to process the payments received from clients of the Macrobiotic Stoner.

b. Through these entities, WING sold prescription drugs to customers in the United States and around the world. These prescription drugs were foreign-sourced versions of mifepristone and misoprostol, which were not versions approved by the United States Food and Drug Administration (FDA) for use in the United States.

c. WING could not legally sell prescription drugs because she was not licensed to do so. WING did not possess a valid wholesale drug distribution license, a valid pharmacy license, or a license to prescribe prescription drugs in New York state, Wisconsin, or any other state. WING also was not duly registered under Section 510 of the Federal, Food, Drug, and Cosmetic Act (FDCA), as a drug manufacturer.

d. WING imported the foreign-sourced prescription drugs in wholesale quantities into the United States from India. WING broke down the bulk shipments, and repackaged them into retail quantities. WING then mailed the foreign-sourced versions of mifepristone and misoprostol to her clients by U.S. Mail. WING intended that the foreign-sourced versions of mifepristone and misoprostol be used by her clients to affect the structure and function of the human body.

e. WING used computers at her home to operate her business, and to communicate with her business clients via email, using two email addresses: macrobiotocstoner@gmail.com and moroccointernationalinc@gmail.com.

f. WING maintained a bank account for Morocco International Inc. at JPMorgan Chase Bank. WING used the PayPal online money transfer system to receive payments from her clients. WING deposited the business receipts from PayPal into her JPMorgan Chase business bank account. In March 2018, WING obtained a merchant account from Square, a credit card processing service, and began accepting credit cards as a source of payment. In June 2018, WING applied for a Western Union business account under the business name Morocco International Inc. On the application, WING

indicated she was in the business of selling jewelry, clothing and housewares imported primarily from Morocco and India, to online customers in the United States.

Legal Background

U.S. Food and Drug Administration – Drug Definitions

g. The United States Food and Drug Administration ("FDA") is the federal agency within the executive branch of the government responsible for protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act (FDCA). Among the purposes of the FDCA is to assure that drugs sold for human use are safe, effective, and bear accurate labeling containing all required information. The FDA's responsibilities under the FDCA include regulating the manufacture, labeling, and distribution of all drugs shipped or received in interstate commerce.

h. Under the FDCA, "drugs" are defined as, among other things, articles intended for use in the cure, mitigation, treatment or prevention of disease in humans (21 U.S.C. § 321(g)(l)(B)); articles intended to affect the structure or function of the body of humans (21 U.S.C. § 321(g)(l)(C)); or articles intended for use as components of other drugs (21 U.S.C. § 321(g)(1)(D)).

i. The term "label" is defined as a display of written, printed, or graphic matter upon the immediate container of any article. (21 U.S.C. § 32l(k)). The term "labeling" is defined as all labels and other printed or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. (21 U.S.C. § 32l(m)).

j. "Prescription drugs" are defined under the FDCA as: (a) those drugs which, because of their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, are not safe for use except under the supervision of a practitioner licensed by law to administer such drug; and (b) those drugs limited by an FDA-approved application to use under the professional supervision of a licensed medical practitioner (21 U.S.C. §§ 353(b)(l)(A) and (B)).

k. A drug is "misbranded" if, among other things: (1) its labeling is false or misleading in any particular manner (21 U.S.C. § 352(a)); or (2) its labeling does not bear adequate directions for use (21 U.S.C. § 352 (f)(l)); or (3) it is an imitation of another drug (21 U.S.C. § 352(i)(2)), or (4) it is offered for sale under the name of another drug (21 U.S.C. § 352(i)(3)); or (5) the drug is a prescription drug dispensed without the valid prescription of a practitioner licensed by law to administer such drug (21 U.S.C. § 353(b)(l).

l. "Adequate directions for use" is further defined by regulation as "directions under which the layman can use a drug safely and for the purposes for which it is intended." (21 C.F.R. § 201.5). Because prescription drugs by definition can only be safely used under the supervision of a licensed medical practitioner, they have to qualify for an exemption to this labeling requirement to be legally distributed in interstate commerce. The exemption is set forth in Title 21, Code of Federal Regulations, Section 201.100, which states that a prescription drug is exempt from the requirement of Title 21, United States Code, Sections 352(f) (that its labeling contain

adequate directions for use) if the following conditions of the exemption are met, including: (1) that the drug be in the possession of persons regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; or (2) in the possession of a retail, hospital, or clinic pharmacy regularly and lawfully engaged in dispensing prescription drugs; or (3) in the possession of a practitioner licensed by law to administer or prescribe such drugs; and (4) the drug was to be dispensed pursuant to a valid prescription. In addition, if the drug was one required under the FDCA to have an approved application prior to distribution, the drug had to bear the FDA-approved labeling.

m. A prescription drug is dispensed only upon the written prescription of a practitioner licensed by law to administer such a drug, or upon an oral prescription of such practitioner, which is reduced promptly to writing and filed by the Pharmacist. The act of dispensing a drug contrary to these requirements results in that drug being misbranded while held for sale. (21 U.S.C. § 353(b)(1)).

n. The FDCA provides that before a "new drug" can be distributed in interstate commerce, its manufacturer must obtain FDA approval of a New Drug Application, an Abbreviated New Drug Application (for generic drugs), or an Investigational New Drug Application (for drugs being researched in humans). To receive approval to market a new drug, the manufacturer must submit information showing that the new drug is safe and effective for its intended use, or for generics to show bioequivalence to the pioneer (brand name) drug. (21 U.S.C. § 355).

o. Under the FDCA, the commission of the following actions constitute a "prohibited act" under the statute:

- The introduction or delivery for introduction into interstate commerce of a misbranded drug. (21 U.S.C. § 331(a));
- The receipt in interstate commerce of any drug that is misbranded and the delivery or proffered delivery thereof for pay or otherwise. (21 U.S.C. § 331(c)); and
- The doing of any act with respect to a drug while such article is held for sale after shipment in interstate commerce which results in the drug being misbranded. (21 U.S.C. § 331(k)).

The Drugs

p. Mifepristone (brand name Mifeprex) is a "drug" within the meaning of Title 21, United States Code, Section 321(g)(1), and a "prescription drug" within the meaning of Title 21, United States Code, Section 353(b)(l). Mifepristone is an FDA-approved drug, and when used together with another drug called Misoprostol, will medically terminate an early pregnancy (up to 70 days or less). Mifepristone is a prescription drug, but is not available to the public through pharmacies; its distribution is restricted to specially qualified, licensed physicians, and the administration of Mifepristone is subject to an FDA Risk and Evaluation Mitigation Strategy (REMS). Among the REMS requirements are that mifepristone may only be dispensed in clinics, medical offices, and hospitals by, or under the supervision of, a certified healthcare

provider, and the healthcare provider must obtain a signed Patient Agreement Form before dispensing mifepristone.

q. Misoprostol (brand name Cytotec) is a "drug" within the meaning of Title 21, United States Code, Section 321(g)(1), and a "prescription drug" within the meaning of Title 21, United States Code, Section 353(b)(l). Misoprostol is an FDA-approved prescription drug used to treat stomach ulcers. The FDA-approved labeling further states in bold lettering: "Cytotec should not be taken by pregnant women to reduce the risk of ulcers induced by nonsteroidal anti-inflammatory drugs (NSAIDs)."

U.S. Department of Homeland Security – Import and Export Regulations

r. The Department of Homeland Security, Customs and Border Protection (CBP) is the agency responsible for administering the laws governing the importation into the United States of merchandise, including drugs.
CBP is also responsible for the enforcement of applicable statues associated with the export of goods from the United States.

s. Federal law requires that, among other things, all merchandise brought into the United States by any individual: (1) be declared to a Customs Officer at the port of first arrival in the United States; (2) be declared on a conveyance en route to the United States on which a Customs officer was assigned for that purpose; or (3) be declared to a pre-clearance office in a foreign country where a United States Customs office was stationed for that purpose.

t. An importer of merchandise into the United States is liable for duties, taxes, and fees on the imported merchandise. The importer of record is

responsible for filing entry documents with the CBP, which classifies the imported merchandise, identifies its value, and provides any other information necessary to enable CBP to assess duties properly, collect accurate statistics, and determine whether other applicable legal requirements, if any, have been met.

u. Whenever drugs falling under the jurisdiction of the FDA are declared or offered from import into the United States, the CBP notifies the FDA to determine whether the drug should be sampled and whether importation of the drug was lawful under the FDCA.

U.S. Postal Service – Mailing Regulations

v. The United States Postal Inspection Service (USPIS) is the law enforcement arm of the U.S. Postal Service (USPS) whose duties include the enforcement of the laws that defend the nation's mail system from illegal or dangerous use, and ensure public trust in the mail.

w. When utilizing the United States Postal Service, an exporter of record is required to complete a United States Postal Service form number 2976 or 2976-A, and list among other items, a detailed description of the contents. The information provided on the form allows CBP to assess duties properly, collect accurate statistics, and determine whether other applicable legal requirements, if any, have been met.

Conspiracy

2. From in or about June 2016 and continuing to on or about June 21, 2018, in the Western District of Wisconsin and elsewhere, the defendant,

URSULA WING,

knowingly and intentionally conspired with other persons, known and unknown to the grand jury, to defraud the United States for the purpose of impeding, impairing, obstructing, and defeating the lawful government functions of the following federal agencies through deceit, craft, trickery and means that were dishonest, more specifically:

a. The U.S. Food and Drug Administration (FDA) in the administration and enforcement of the laws and regulations pertaining to the FDCA.

b. The U.S. Department of Homeland Security, Customs and Border Protection agency (CBP) in the administration and enforcement of the laws and regulations pertaining to the import and export of merchandise, including drugs, into and out of, the United States.

c. The U.S. Postal Inspection Service (USPIS) in the administration and enforcement of the laws pertaining to the use of the U.S. mails.

Manner and Means

The manner and means by which the conspiracy was sought to be accomplished included, among others, the following:

3. It was part of the conspiracy that WING illegally smuggled into the United States misbranded prescription drugs from India. WING obtained versions of misoprostol and mifepristone which, according to the packaging, were manufactured by Cipla Ltd in India. These foreign-source drugs were not approved by the FDA for distribution in the United States. This imported merchandise would contain a U.S.

Customs Declaration Form CN22 falsely stating: (1) the contents were "personal supply medication;" and (2) the contents did not contain any dangerous articles or articles prohibited by postal or customs regulations.

4. It was further part of the conspiracy that WING sold these misbranded prescription drugs to customers in the United States and around the world. Because WING was not licensed to prescribe or distribute prescription drugs, WING used a secret webpage called "My Secret Bodega," on her Macrobiotic Stoner blog at: www.macrobioticstoner.com/my-secret-bodega.com, to hide her activities from the FDA, CBP and USPIS. On this page, WING offered misoprostol and mifepristone, individually, in various quantities and prices. WING also offered misoprostol and mifepristone, together as a "MTP Kit," in various quantities and prices.

5. It was further part of the conspiracy that WING attempted to hide her activities from the FDA, CBP and USPIS by disguising the nature of her sales of the misbranded prescription drugs that were ordered on her secret webpage. First, WING created a fake company called "Fatima's Bead Basket" which she listed as the shipper on the envelope going to the customer. Second, WING inserted a necklace or other item of jewelry in the shipping envelope to serve as the cover piece of merchandise being mailed to the customer. Third, WING packaged the misbranded prescription drugs in a smaller packet that was in a hidden panel and taped to the inside of the shipping envelope. Fourth, WING disguised the nature of the item being purchased by listing on the invoice alternate jewelry product names, each of which had a code to indicate the actual item being ordered. These jewelry product names included: "Gold electroplate

twisted multi-rope collar necklace," which stood for a "MTP Kit of 1 mifepristone 200 mg pill and 4 misoprostol 200 mg pills."

6. It was further part of the conspiracy that WING mailed these misbranded prescription drugs from the United States to customers around the world, and falsely characterized the exports on the US Customs Forms as jewelry.

7. It was further part of the conspiracy that WING created a fake online jewelry business called Morocco International at www.morocointernational.com and a fake merchant processing portal at https://moroccointernational.com/checkout/ for use as a cover for selling the misbranded prescription drugs on her secret webpage. By creating this fake merchant processing portal, WING allowed her Macrobiotic Stoner clients to pay for the misbranded drugs using their credit cards, with the sales showing up on the merchant account as jewelry, and not mifepristone or misoprostol.

Overt Acts

In furtherance of the conspiracy, and to accomplish its objectives, the following overt acts were committed in the Western District of Wisconsin, and elsewhere:

8. On or about January 16, 2018, WING caused to be mailed within the United States, misbranded prescription drugs from New York City, New York to Crystal, Minnesota (USPS Tracking Number 9405809699937270383537);

9. On or about January 27, 2018, WING caused to be mailed within the United States, misbranded prescription drugs from New York City, New York to Portage, Wisconsin (USPS Tracking Number 9405809699938161709504);

10. On or about January 30, 2018, WING caused to be mailed within the United States, misbranded prescription drugs from New York City, New York to Wisconsin Rapids, Wisconsin (USPS Tracking Number 9405809699939660431873);

11. On or about June 8, 2018, WING caused to be imported into the United States, misbranded prescription drugs from New Delhi, India to New York City, New York (EMS Tracking Number ED877904579IN);

12. On or about June 15, 2018, WING caused to be imported into the United States, misbranded prescription drugs from New Delhi, India to New York City, New York (EMS Tracking Number ED877910163IN);

13. On or about June 15, 2018, WING caused to be imported into the United States, misbranded prescription drugs from New Delhi, India to New York City, New York (EMS Tracking Number ED877914386IN);

(All in violation of Title 18, United States Code, Section 371).

COUNT 2

1. Paragraph 1 of Count 1 is incorporated here.

2. From on or about January 29, 2018 to on or about February 2, 2018 in the Western District of Wisconsin, and elsewhere, the defendant,

URSULA WING,

with the intent to defraud and mislead, introduced, delivered for introduction, and caused the introduction and delivery for introduction into interstate commerce, from the State of New York to Wisconsin, prescription drugs, mifepristone and misoprostol, that were misbranded, more specifically: (1) they were dispensed without a valid

prescription from a practitioner licensed by law to administer such drugs (21 U.S.C. § 353(b)(1)); and (2) the labeling of the drugs lacked adequate directions for use by a lay person (21 U.S.C. § 352(f)(1)).

(All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2)).

FOREFEITURE ALLEGATION

1. Upon conviction on Count 1 or Count 2 of this indictment, the defendant URSULA WING, shall forfeit to the United States, pursuant to 21 U.S.C. § 334(d)(3) and 28 U.S.C. § 2461(c), all quantities of the misbranded drugs distributed by WING via the Macrobiotic Stoner website, as evidenced by her PayPal and Square deposits.

2. If any of the property described above, as a result of any act or omission of the defendant[s]:

a. cannot be located upon the exercise of due diligence;
b. has been transferred or sold to, or deposited with, a third party;
c. has been placed beyond the jurisdiction of the court;
d. has been substantially diminished in value; or
e. has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States of America, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c), to seek forfeiture of any other property of the defendant up to the value of the property subject to forfeiture, that is $61,753.

(All in violation of Title 21, United States Code, Sections 334(d)(3), 853(p) and Title 28, United States Code, Section 2461(c)).

A TRUE BILL.

PRESIDING JUROR

Indictment returned: 6/26/2019

For SCOTT C. BLADER
United States Attorney